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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/703,350	Applicant(s) MEHRABAN ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

The selection of any one group (specifically, Groups 1-559) below requires applicant to identify the PA (i.e. PA molecules 1-27) molecule of choice as each PA molecule represents an independent and or distinct invention.

Groups 1-27:

Claims 1-7, drawn to a method of assessing the efficacy of an angiogenic disorder treatment in a subject comprising providing from the subject a test cell population capable of expressing ONE nucleic acid selected from PA:1-27 wherein the test cell population is provided *ex vivo* or *in vitro*, classified in class 434, subclass 6.

Groups 28-55:

Claims 1-5, 8, drawn to a method of assessing the efficacy of an angiogenic disorder treatment in a subject comprising providing from the subject a test cell population capable of expressing ONE nucleic acid selected from PA:1-27 wherein the test cell population is provided *in vivo*, classified in class 424, subclass 9.1.

Groups 56-83:

Claims 9-15, 27-29, drawn to a method of diagnosing an angiogenic disorder in a subject comprising providing from the subject a test cell population capable of expressing ONE nucleic acid selected from PA:1-27 wherein the test cell population is provided *in vitro* or *ex vivo*, classified in class 424, subclass 9.1.

Groups 84-111:

Claims 9-13, 16, drawn to a method of diagnosing an angiogenic disorder in a subject comprising providing from the subject a test cell population capable of expressing ONE nucleic acid selected from PA:1-27 wherein the test cell population is provided *in vivo*, classified in class 424, subclass 9.1.

Groups 112-139:

Claims 17-26, drawn to a method of identifying a test therapeutic agent for treating an angiogenic disorder in a subject comprising contact with a test therapeutic agent and providing from the subject a test cell population capable of expressing ONE nucleic acid selected from PA:1-27, classified in class 424, subclass 9.2.

Groups 140-167:

Claims 30-34 drawn to a method of treating an angiogenic disorder comprising administering to a patient an agent that modulates the expression or activity of

ONE nucleic acid selected from PA:1-27 wherein said agent is an antisense molecule, classified in class 514, subclass 44.

Groups 168-195:

Claims 30-34 drawn to a method of treating an angiogenic disorder comprising administering to a patient an agent that modulates the expression or activity of ONE nucleic acid selected from PA:1-27 wherein said agent is selected from the group consisting of a peptide, a PA polypeptide agonist, a PA polypeptide antagonist, or a peptidomimetic, classified in class 424, subclass 184.1.

Groups 196-223:

Claims 30-34 drawn to a method of treating an angiogenic disorder comprising administering to a patient an agent that modulates the expression or activity of ONE nucleic acid selected from PA:1-27 wherein said agent is selected from the group consisting of a small molecule or other drug, classified in class 514, subclass 1.

Groups 224-251:

Claims 30-34 drawn to a method of treating an angiogenic disorder comprising administering to a patient an agent that modulates the expression or activity of ONE nucleic acid selected from PA:1-27 wherein said agent is selected from the group consisting of an antibody, classified in class 424, subclass 130.1.

Groups 252-279:

Claim 35, drawn to a kit comprising one or more reagents for detecting ONE nucleic acid sequences selected from the group consisting of PA:1-27, classified in class 435, subclass 810.

Groups 280-307:

Claims 36, 42-46, 49-50 drawn to an isolated nucleic acid probe to detect ONE nucleic acid sequence of PA:1-27, isolated nucleic acids with at least 75% identity to ONE nucleic acid of PA:1-27, and ONE therapeutic composition thereof including additional active ingredients, classified in class 536, subclass 23.5; class 514, subclass 44.

Groups 308-335:

Claims 37-41, 47-48 drawn to an isolated polypeptide at least 80% identical to ONE polypeptide comprising an amino acid sequence of PA:1-27, and ONE therapeutic compositions thereof, including additional active ingredients, classified in class 530, subclass 350; class 514, subclass 2.

Groups 336-363:

Claims 51-52, drawn to ONE therapeutic agonist or antagonist of a PA polypeptide and an additional active ingredient, classified in class 514, subclass 1.

Groups 364-391:

Claims 53, drawn to a kit comprising ONE therapeutic composition selected from the group consisting of one PA polypeptide, or one agonist of a PA polypeptide or one antagonist of a PA polypeptide, classified in class 435, subclass 810.

Groups 392-419:

Claim 54, drawn to a method of treating an angiogenic disorder comprising administering ONE therapeutic compound comprising ONE polypeptide, classified in class 424, subclass 184.1.

Groups 420-447:

Claim 55, drawn to a method of treating an angiogenic disorder comprising administering ONE therapeutic compound comprising ONE nucleic acid molecule, classified in class 514, subclass 44.

Groups 448-475:

Claim 56-57, drawn to a method for inhibiting angiogenesis in a mammal comprising administering one PA polypeptide, or one agonist of a PA polypeptide or one antagonist of a PA polypeptide, classified in class 424, subclass 184.1.

Groups 476-503:

Claim 58-59, drawn to a method for stimulating angiogenesis in a mammal comprising administering one PA polypeptide, or one agonist of a PA polypeptide or one antagonist of a PA polypeptide, classified in class 424, subclass 184.1.

Groups 504-531:

Claim 56-57, drawn to a method for inhibiting angiogenesis in a mammal comprising administering one anti-PA antibody, classified in class 424, subclass 130.1.

Groups 532-559:

Claim 58-59, drawn to a method for stimulating angiogenesis in a mammal comprising administering one anti-PA antibody, classified in class 424, subclass 130.1

Group 560:

Claims 60-62, 65, drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence at least 75% identical to a nucleic acid sequence encoding the polypeptide of SEQ ID NO:72, a vector thereof, a host cell thereof, and a pharmaceutical composition thereof, classified in class 536, subclass 23.5; class 435, subclasses 320.1, 325; class 514, subclass 44.

Group 561:

Claims 63, 66, drawn to an isolated polypeptide at least 80% identical to a polypeptide comprising an amino acid sequence of SEQ ID NO:72, and pharmaceutical composition thereof, classified in class 530, subclass 350; class 514, subclass 2.

Group 562:

Claim 64, drawn to an antibody and fragments thereof, classified in class 530, subclass 387.1.

Group 563:

Claim 67, drawn to a method of detecting a nucleic acid in a sample comprising contacting the sample with a compound that selectively binds to the nucleic acid, classified in class 435, subclass 6.

Group 564:

Claim 68, drawn to a method of detecting a polypeptide in a sample comprising contacting the sample with a compound that selectively binds to the polypeptide, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups 252-391, and 560-562 represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

The inventions of Groups 1-251,392-559, and 563-564 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The invention of Groups 280-307 and the method of Groups 1-139, and 420-447 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid products as claimed can be used in a materially different process such as affinity chromatography.

The invention of Groups 308-391 and the method of Groups 168-195, 392-419, 448-503 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case

the polypeptide products as claimed can be used in a materially different process such as affinity chromatography.

The invention of Group 560 and the method of Group 563 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid product as claimed can be used in a materially different process such as affinity chromatography.

The invention of Group 561 and the method of Group 564 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a materially different process such as affinity chromatography.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Species Elections:

Claims 26 and 34 are generic to a plurality of disclosed patentably distinct species comprising the disorders listed in Claim 26 and or 34 which differ at least, in organ sites, etiology, and pathology.

Claims 48 50, and 52 are generic to a plurality of disclosed patentably distinct species comprising the following agents: a cardiovascular agent, and endothelial agent, an angiogenic agent, or angiostatic agent.

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
August 2, 2002